

AMENDMENTS TO THE DRAWINGS:

The attached sheet of drawings includes changes to Fig. 3. This sheet, which includes Fig. 3, replaces the original sheet including Fig. 3. Previously omitted reference numerals 303, and 305 have been added to Figure 3. Support for this amendment is found in paragraph [0050] of the specification. No new matter has been added

Attachment: Replacement Sheet

Annotated Sheet Showing Changes

REMARKS

Applicants respectfully request reconsideration of this application in view of the foregoing amendments and the following remarks.

Claims 1, 3, 6, 8, 11, 26, 28 42-47, and 49 are pending in this application and have been rejected. To expedite the application and clarify the meaning of the term “oriented”, claims 1, 6, and 49 have been amended, and previously omitted element number 305 has been added to amended Figure 3.

Applicants believe that the application is in form for allowance and as such allowance is respectfully requested in order to avoid further Office Actions and the need to pursue an appeal. The claims are clearly distinguishable from the references cited in the present Office Action as well as references cited in previous Office Actions.

1. Rejection under 35 U.S.C. §102 for Fischell

Independent claim 1, 6, 42-47, and 49 have been rejected under 35 U.S.C. §102 as being anticipated by U.S. Patent No. 6,190,403 (“Fischell”). Applicants strongly traverse these rejections as follows.

It is clear by plain meaning what is meant by the term “oriented” as it relates to the circumferential orientation of the continuous, higher frequency, loops. The term “oriented” has a plain meaning in the context used in the claims of “aligned or positioned with respect to a point or system of reference” (The American Heritage Dictionary of the English Language, Fourth Edition). Therefore, the ordinary meaning of this term makes clear that the loops are running (or are oriented) in the circumferential direction. To expedite the application, applicants have amended the claims to clarify that the higher frequency, sinusoid is oriented about a circumferential, rather than longitudinal axis. Further, Applicants have amended Figure 3 to clarify the term “oriented”. Support for this clarification is found in paragraph [0050] of the specification. It is well settled in that “drawings alone may provide a ‘written description’

of an invention as required by §112, first paragraph.” Vas-Cath v. Mahurkar 935 F.2d 1555, 1565, 19 USPQ.2d 1111, 1118 (Fed. Cir. 1991). Therefore, the Examiner may refer to the drawings in addition to the specification to determine the scope of the claim term “oriented”.

In view of the amended drawing, amended claims 1, 6, and 49 clearly recite a continuous, generally sinusoidal pattern of loops of a higher frequency oriented about a *circumferential* axis. Paragraph [0050] of the specification discloses “[a] third loop containing section 303 extending along line 305 has loops occurring at a second frequency that is higher than said first frequency.” As is clear in the drawing, line 305, as well as lines 301 and 302, represents the circumferential axis of the pattern which extends in the circumferential direction.

In contrast, Fischell specifically discloses an arrangement oriented about the *longitudinal* axis. A longitudinally oriented arrangement is not oriented about a circumferential axis. The generally sinusoidal section of the higher frequency link pattern, asserted by the Examiner, is thus oriented orthogonal relative to the surrounding, lower frequency connector. In contrast, the corresponding higher frequency generally sinusoidal loop containing section in the current invention is oriented parallel to the surrounding, lower frequency generally sinusoidal loop containing section. The cited Fischell reference is therefore distinguishable from the current invention.

2. Rejection under 35 U.S.C. §103 for Jayaraman in View of Von Oepen

Claims 1, 6, 11, 42-47 and 49 have been rejected under 35 U.S.C. §103 as being unpatentable over “Jayaraman” (U.S. Patent No. 6,162,245) in view of “Von Oepen” (U.S. Patent No. 6,193,747). Applicants respectfully disagree with this rejection.

The Jayaraman reference lacks the longitudinal flexibility of the current invention. The Jayaraman reference discloses straight connectors between loop

containing sections to form a rigid, non-flexible stent. (See Jayaraman Col. 5, lines 10-15). As noted in the Office Action dated May 25, 2005, the Jayaraman stent is not, in fact, a stent at all, but rather a scaffolding which is attached to a graft material. Because the tops and bottoms of the loops of the Jayaraman structure are fastened to the graft material, there can be no movement of these loops without tearing or otherwise damaging the graft material. This is quite in contrast to the flexible nature of the instant invention. Therefore, Jayaraman cannot elongate or shorten so as to maintain constant cell area as recited in the claims.

Further, the “3rd loop containing section/2nd circumferential band of a 2nd frequency,” as seen in Jayaraman Fig. 30 (as characterized in the pending Official Communication) actually contributes more rigidity to the stent and is less flexible than the low frequency loops. The higher frequency sections, as seen in Jayaraman Fig. 30, are more rigid than the lower frequency sections because there is more material per unit area of stent in these high frequency sections. This is distinguishable from the claimed invention in that the lower frequency circumferential band of the instant stent has wider struts than the struts of the high frequency bands, making the high frequency bands more flexible than the low frequency ones. Nothing in Jayaraman reference teaches or suggests that the higher frequency sections can provide the added flexibility to the structure.

Moreover, Von Oepen does not teach or suggest a reason why the rigidity of the high frequency bands of Jayaraman should be changed. Therefore there is no motivation to combine these references.

The combination of Jayaraman and Von Oepen does not render obvious a stent as recited in the claims of the current invention. One skilled in the art reading these references would not be led to the instant invention because combining the references would not achieve the functional effect of longitudinal flexibility both before and after stent expansion. Therefore, Jayaraman in view of Von Oepen does not teach or suggest the claimed stent design of the present invention.

3. Rejection under 35 U.S.C. §103 for Jayaraman and Von Oepen in view of Yang

Claims 3 and 8 have been rejected under 35 U.S.C. §103 as being unpatentable over Jayaraman and Von Oepen, and further in view of “Yang” (U.S. Patent No. 6,120,847). Applicants respectfully disagree with this rejection.

The examiner acknowledges that Jayaraman and Von Oepen do not disclose a stent covered with medicine. As discussed above, Jayaraman in view of Von Oepen does not teach or suggest the claimed stent. The Jayaraman reference does not teach or suggest wider low frequency loops and Von Oepen provides no reason to switch the radially supporting loops from the high frequency loops to the low frequency loops. Yang does not remedy these deficiencies.

As discussed in the Office Action dated May 25, 2005, Yang discloses surface treatments that eliminate surface imperfections on a medical device having a drug release coating. Yang eliminates these imperfections by a dipping or spraying process using a solvent carrier to incorporate a therapeutic agent within a polymer matrix.

The combination of Jayaraman and Von Oepen with Yang does not render obvious a stent having a coating as recited in the claims. One skilled in the art reading these references would not be led to the instant invention, because none of the cited references, in any combination teach or suggest the basic stent design of the present invention.

The present invention provides a structure which more evenly contacts a vessel wall so as to provide an even distribution of medicine to a vessel wall. Nothing in Yang alone or in combination with Jayaraman and Von Oepen teaches or suggests such a concept. Yang does not teach or suggest using the claimed stent design to provide a more even dose being applied to the inside wall of a bodily lumen.

Because Jayaraman and Von Oepen in view of Yang does not teach or suggest the claimed stent structure or the use of stent structure to provide an even distribution of medicine to a vessel wall, applicants assert that these references alone or in combination do not anticipate or render the claims obvious.

Reconsideration and withdrawal of the rejections is respectfully requested.

4. Rejection under 35 U.S.C. §103 for Brown in View of Von Oepen

Claim 26 has been rejected as obvious under 35 U.S.C. §103 over “Brown et al.” (WO 00/30563 or US 20020007212 A1) in view of Von Oepen. Applicants respectfully disagree with this rejection.

While it is agreed that Brown does not disclose the limitation of wider struts in the lower frequency bands for handling radial force applied by the stent to a blood vessel, we respectfully disagree with the Examiner’s contention that Brown discloses substantially all other limitations in this claim.

Brown has additional elements and therefore falls outside the scope of claim 26. Von Open doesn’t remedy this deficiency. Brown does not teach or suggest a coronary stent as recited in claim 26. For Brown to teach a coronary stent, the number of loops per cell would need to be much smaller than that disclosed in Brown. As described in this publication, Brown has large cells in a 3:5 ratio of loops. In order for this stent to be uniformly flexibly, it would need to have at least 3 connecting struts; hence a loop ratio of 9:15 around the circumference of the stent. Fifteen loops are equal to 30 struts which create too much bulk to be crimpable into a diameter small enough to fit into a coronary vessel. The large stent diameter of Brown results in a stent which cannot be used as a coronary stent because it cannot be sufficiently crimped.

In addition, Brown discloses cylindrically shaped segments comprising the pattern. The present invention is not limited to such a layout, instead disclosing a plurality of cell structures, including, but not limited to, a triangular-shaped cell structure.

The departure from the cylindrical layout of Brown, as discussed in reference to Von Oepen above, allows dimensional stability and longitudinal flexibility in both the expanded and non-expanded states by removing stress points caused by a rigid stent in its expanded form. Brown is therefore distinguishable from the current invention.

In addition, Von Oepen also does not teach or suggest that the higher frequency sections can provide flexibility to the structure. The current invention provides flexibility in the expanded state by disclosing a continuous, non-longitudinally oriented loop containing section where the generally sinusoidal patterns are oriented about a circumferential axis. Von Oepen does not disclose a flexible higher frequency section, but rather a series of hairpin arcs (or U- or V-shaped "links") oriented about a longitudinal axis and not about a circumferential axis. The current invention is therefore distinguishable from the Von Oepen reference.

The combination of Brown and Von Oepen does not render obvious a stent as recited in the claims of the current invention. One skilled in the art reading these references would not be led to the instant invention because combining the references would not achieve the functional effect of longitudinal flexibility both before and after stent expansion. Therefore, neither Brown nor Von Oepen teach or suggest the basic stent design of the present invention.

For at least these reasons, reconsideration and withdrawal of the rejections is respectfully requested.

CONCLUSION

In view of the foregoing, the present invention as recited in the claims presented herein is believed patentably distinct over the art of record and Applicants respectfully request that the respective rejections be withdrawn and the application be allowed as the application is hereby placed in condition for allowance.

If any outstanding issues remain, however, the Examiner is invited to contact the undersigned at the telephone number below.


AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees that may be required for this amendment, or credit any overpayment to Deposit Account No. 13-4500, Order No. 4303-4005.

Respectfully submitted,
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ANNOTATED SHEET
SHOWING CHANGES

